Board of Pharmacy

Final Statement of Reasons

Subject Matter of Proposed Regulation: Pharmacy Technicians Checking Pharmacy Technicians

Title 16 Sections Affected: 1793.7 and 1793.8

Hearing Date: April 26, 2006

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the board's position regarding pharmacy technicians checking pharmacy technicians.

Summary of Comments Received During the 45-Day Comment Period:

The board received 39 letters in support of the proposed regulation change during the 45-day comment period.

The board received two written comments expressing concern about the proposed changes.

1. In a letter dated April 17, 2006, Barry Broad, representing the United Food and Commercial Workers Union, Western States Council, states that the organization is opposed to the regulations proposed by the Board of Pharmacy. Specifically Mr. Broad alleges that the board is overreaching its authority in promulgating these particular regulations.

   The board disagrees. Business and Professions Code section 4005 clearly establishes the board's authority to adopt rules and regulations that are not inconsistent with the law of this state, as necessary for the protection of the public. Specifically, Business and Professions Code section 4005(a) includes that the board has the right to adopt regulations pertaining to the practice of pharmacy as well as those pertaining to establishments wherein any drug or device is compounded, prepared, furnished or dispensed. The proposed regulations directly pertain to the practice of pharmacy as it occurs in hospitals wherein drugs are prepared, furnished and dispensed. These drugs may also be compounded depending on the policies and procedures of the acute care facility. In addition to the clear authority stated above, the board also bases its authority on two separate written legal opinions, both of which also confirm the board's authority to pursue the proposed regulations. Staff counsel

from the Department of Consumer Affairs concludes after researching the matter that a pharmacist is not required to personally check unit dose cassettes and floor and ward stocks filled by a pharmacy technician in an inpatient pharmacy setting. Instead the pharmacist may authorize another pharmacy technician to perform such checks. In addition, Legislative Counsel of California also reviewed the issue and concluded that a regulation may be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 (recodified in 1997 to Business & Professions Code 4115 (d)) of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians. (Copies of the two written legal opinions are provided under Background Information as listed in the Table of Contents.) Current staff counsel has also affirmed the board's authority to promulgate these regulations. Furthermore, Business and Professions Code section 4115(d) specifically requires the board to adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist.

Mr. Broad states that the proposed regulations are inconsistent with existing state law and, rather than providing additional consumer protection will likely increase the risk of harm to the public.

The board disagrees with this assertion. The proposed regulations further define the exact role a pharmacy technician may take in an acute care pharmacy setting as required in Business and Professions Code section 4115(d). The proposed regulations will not increase the risk of harm borne to the public. In fact, to the contrary, several published articles and studies show that the converse it true; hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. A UCSF study documents that the accuracy checking rate of pharmacy technicians is 99.88%[3]. A follow-up study also conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified. Other testimony provided to the board also refutes Mr. Broad's assertion, for example compelling statistics supporting technician checking technicians were provided as testimony during the board's January 2006 Licensing Committee Meeting by Susan

Ravnan, Pharm.D. (A copy of the testimony and substantiating articles are included in the background information.)

Mr. Broad continues that existing law specifies the duties which may only be undertaken by licensed pharmacists and those which may be undertaken by licensed pharmacist technicians under the direct supervision of a pharmacist.

The proposed regulations are not in conflict with existing law. Business and Professions Code section 4115 (d) requires the board to adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist.

Mr. Broad states that Business and Professions Code section 4115 (a) limits the duties which may be undertaken by a pharmacy technician to "…nondiscretionary tasks, only while assisting and under the direct supervision and control of a pharmacist" and states that Business and Professions Code section 4115(c) specifies that pharmacy technicians are not authorized "to perform any act requiring the exercise of professional judgment by a pharmacist."

The board agrees with Mr. Broad's citations of the above Business and Professions Code references, but not the assertion that the proposed regulation is in conflict with existing law. Business and Professions Code section 4023.5 specifies that "direct supervision and control" means that a pharmacist is on the premises at all times and is fully aware of all activities performed by either a pharmacy technician or intern pharmacist. There is no language in the proposed regulation that is in conflict with this definition of direct supervision. There is nothing in this definition that requires direct line of sight supervision. Additionally, this regulation does not allow a pharmacy technician to perform duties outside of his or her defined scope of practice. Double checking the unit dose and floor ward stock is a non-discretionary task.

Mr. Broad states that B & P section 4115 (h) specifies that pharmacists "shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist."

The board agrees with this statement.

Mr. Broad states that existing regulations support the limitations on pharmacy technicians imposed by statutory law and he cites California Code of Regulations section 1793.7 which states that "Any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of

pharmaceuticals, must be verified and documented in writing by a pharmacist."

The board agrees with the above citation. Mr. Broad failed to cite the second half of the relevant subsection he quoted, CCR 1793.7(a). The next sentence in the subsection makes an exception for the preparation of prescriptions for an inpatient or a hospital (an acute care setting) and for an inmate of a correctional facility, where the pharmacist is not required to indicate verification of a prescription by initialling the prescription label before the medication is provided to the patient. Furthermore, CCR 1793.7 (b) states that a pharmacy technician must work under the direct supervision of a pharmacist in such a relationship that the supervising pharmacist is fully aware of all activities involved in the preparation and dispensing of medications, including maintenance of appropriate records. Subsection (b) is a safeguard to ensure that a pharmacy technician does not complete tasks outside of the scope of a technician's license.

Mr. Broad concludes this portion of his comments and states that both existing statutory and regulatory provisions are clear in the limitations imposed on what pharmacy technicians may and may not do, and are clear in the supervisory role that must be played by the pharmacist. He states that it would be contradictory to existing law to allow pharmacy technicians to check the work of other pharmacy technicians in lieu of that oversight being undertaken by pharmacist and that it would be contrary to the provision of existing statutory law which limits the authority of the board of promulgate regulations.

Again the board disagrees with Mr. Broad's conclusions. There is not a single statute that prevents or limits the non-discretionary tasks a pharmacy technician can perform. The proposed regulation is designed to better define in what circumstances a pharmacy technician can verify the work of another pharmacy technician; there is no professional judgment used to perform this task. These duties must be performed under the direct supervision and control of a pharmacist as defined in statute. Furthermore, the board clearly has the authority to promulgate regulations as detailed in Business and Professions Code section 4005 as supported by two separate written legal opinions as well as current staff counsel and as required in Business and Professions Code section 4115 (d).

Mr. Broad then provides a regulatory history documenting that this is not the first time that regulations regarding the subject matter currently proposed have been considered by the board. Specifically in 1997 the UCSF School of Pharmacy, in conjunction with Cedars-Sinai Medical Center and Long Beach Memorial Medical Center petitioned the board to grant a waiver of the California Code of Regulations requiring licensed pharmacists to check unit does cassettes filed by pharmacy technicians in

the inpatient hospital facility setting. Mr. Board continues that the board granted the waiver and an experimental program was implemented.

The board agrees that a petition was filed. This petition however was submitted in March 1998 to be considered at the board's May 1998 board meeting. The board granted a waiver as allowed in California Code of Regulations 1731. At the May 1998 board meeting, the board did grant a waiver of the California Code of Regulations to the UCSF School of Pharmacy in conjunction with Cedars-Sinai Medical Center and Long Beach Memorial Medical Center to evaluate the use of board registered pharmacy technicians in a unit dose drug distribution system. (A copy of the waiver request and relevant board meeting minutes is included in Background Information.)

Mr. Broad raises three concerns about the study results in his letter. First he indicates that it is not clear if the results of the study upon which this regulatory proposal relies are weighted to reflect the substantial difference in the number of pharmacist participants and dose checks as opposed to the number of pharmacy technician participants and dose checks and concludes that if not, it is impossible to know what the actual accuracy rate differential is.

There are several studies and published articles that document the benefits of a pharmacist's role in direct patient care. The board is not moving forward with the proposed regulations based solely on the study conducted by UCSF School of Pharmacy in conjunction with Cedars-Sinai Medical Center (CSMC) and Long Beach Memorial Medical Center (LBMCC) (UCSF study). However, the results of the UCSF study[3] further verify that the use of pharmacy technicians as proposed in the regulation is in the best interest of public protection. This study was subject to peer review and was designed to determine the effectiveness of using specially trained pharmacy technicians to check the work of other technicians in a limited capacity in acute care pharmacy settings.

Mr. Broad then states that it is not sound public policy, to rely on such a small study.

The board is not moving forward with the proposed regulations based solely on the UCSF study[3]. As indicated above, there are several studies and published articles that document the benefits of a pharmacist's role in direct patient care. The results of the UCSF study[3] further verify that the use of pharmacy technicians as proposed is in the best interest of public protection. There currently are five states that allow pharmacy technicians to be used in the proposed or very similar capacity. In Minnesota the program has been in effect over 14 years with no complaints, and in Kentucky technicians have checked technicians with no complaints in over

ten years. Additionally, the American Society of Health-System Pharmacists and the California Society of Health-System Pharmacists support the role of the technician in checking unit dose medication cassettes. (Professional policy 9801, October 1998.)

Mr. Broad proceeds to document that the differential in accuracy rate was only 0.3% - - with both groups having an above 99% accuracy rating and concludes that the study fails to show a marked improvement of the pharmacy technicians over the pharmacists and fails to show that improvement in this arena is imperative, as both groups had above a 99% accuracy rating.

The UCSF study[3] was not designed to document that a pharmacy technician is more proficient than a pharmacist in checking unit dose medications. Rather is was designed to determine if a pharmacy technician could be trained to complete the task as proficiently as a pharmacist, thereby allowing the pharmacist to be redeployed to become part of a patient's direct care team. This study clearly documents that technicians can complete this nondiscretionary tasks as proficiently as pharmacist.

Mr. Broad next details minutes from two board meetings. He states that at the October 15 & 16, 2001, board meeting there was a lengthy discussion of adopting similar regulations. The minutes included comments, which referenced from Deputy Attorney General William Marcus' opinion that the board does not have the authority to promulgate a regulation of this nature. Mr. Broad continues on to state that during the October 24 & 25, 2002 board meeting, the board decided that the proposed regulation would require legislation.

This is not an accurate reflection of what occurred. Mr. Broad failed to note in his reference that in response, then Deputy Attorney General Ron Diedrich stated that there is no formal Attorney General's Opinion on this issue and that a deputy attorney general's comments are not to be considered an official opinion issued by the AG's Office, contrary to what was inferred by Mr. Broad's statement. Additionally, at the October 2002 board meeting, the board did not determine that the proposed regulation would require legislation. Rather, pending legislation was introduced independent of the board and as such the board delayed pursuing the regulation to allow the legislative process to run its course. (Relevant portions of both meeting minutes are included in Background Information in this rulemaking file.)

Mr. Broad concludes this portion of his letter stating that it is highly suspect that the Board would determine at a public hearing in 2002 that it

did not have the authority to promulgate such regulations, then propose the same regulations a mere four years later.

The board has never determined that is does not have the authority to promulgate these proposed regulations. Mr. Broad's statement indicating as such is an inaccurate representation of the board's action taken at the October 2002 board meeting.

Mr. Broad then provides a legislative history of this subject. Specifically he states that two pieces of legislation, SB 393 and SB 592 introduced in 2003 and 2005 respectively, would have authorized general acute care hospitals to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians. Mr. Broad concludes that both bills were supported by the Board of Pharmacy, which presumably believed that a statutory change was necessary in order to permit technicians to check the work of other technicians without the intervention of a pharmacist.

This is an incorrect conclusion made by Mr. Broad. To the contrary, the board recognized that statutory authorization for technicians checking technicians would accomplish the same result as if the board promulgated a regulation to authorize this.

Mr. Broad states that if one reviews the regulatory and legislative history of this proposal it becomes clear that proponents have made failed attempts to make the same change via both the legislative and regulatory process and that it becomes evident that there are valid arguments which have precluded passage of this proposal via both the legislative and regulatory setting.

The board again disagrees with Mr. Broad's conclusions. The board was not the sponsor of either of the above-cited pieces of legislation. Mounting evidence continues to support the benefits to patients to use technicians in this capacity especially when pharmacists are redirected to perform non-clerical duties with other health care practitioners.

Mr. Broad cites Business & Professions Code section 4001.1 and then states that the proposed regulation will not promote protection of the public, and, to the contrary may result in increased dispensing error rates and associated detrimental impact to patients in the acute care setting.

An article published in the Journal of the American Medical Association entitled "Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit"[2] concludes that the presence of a pharmacist on rounds as a full member of the patient care team in a medical ICU was associated with a substantially lower rate of adverse

drug events caused by prescribing errors. A second article entitled "Pharmacists on Rounding Teams Reduce Preventable Adverse Drug Events in Hospital General Medicine Units"[5] also concludes that pharmacist participation with the medical rounding team on a general medicine unit contributes to a significant reduction in preventable adverse drug events. In a report published entitled "Evaluating the Accuracy of Technicians and Pharmacist in Checking Unit Dose Medication Cassettes,"[3] the study demonstrates that pharmacy technicians who had been trained and certified in a closely supervised program that incorporates quality assurance mechanisms could safely and accurately check unit dose medication cassettes filled by other technicians. These studies and articles as well as several other studies show that hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. A follow-up study conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified.. The public benefit of redirecting pharmacists away from completing the nondiscretionary check of medication that could be completed by another pharmacy technician results in allowing the pharmacist to be involved in direct medication management during a portion of their work shift significantly improving patient outcomes.

Mr. Broad states that patients in an acute care setting are generally those in greatest need of a heightened level of care and are often prescribed multiple medications, which if taken improperly or in the wrong combination could prove fatal. He concludes that it does not stand to reason that pharmacy technicians rather than pharmacists should be checking the work of other pharmacy technician in the acute facility setting.

The board believes the pharmacist is better deployed elsewhere in the hospital. By allowing a pharmacy technician to check the work of other technicians, the pharmacist is then available to ensure the appropriate administration of medications on the floors and to work collaboratively with both treating physicians and nurses involved in the direct patient care. Pharmacists are the safety net for medical staff and nursing staff dependent on the medication use process. If pharmacists have to perform non-discretionary tasks, they are not then available to take care of

patients. Hospital pharmacists have responsibilities for assuring that all drug orders are appropriate in the context of the patient. Pharmacists have access to all of the medical information including progress notes, lab results, etc. Hospitalized patients generally have multiple drug orders and if used incorrectly or if dosed incorrectly, these medications could result in immediate patient harm. Further, the number and different types and complexity of medications available to hospital patients is far more than in a retail or outpatient setting. There is also a host of medications given to hospital patients that require very careful dosing administration and monitoring; these drugs do not exist in the outpatient setting, including drugs issued in the ICUs and drugs that are only available in parenteral form that require extensive monitoring. Pharmacists available in direct patient care prevent adverse drug events, deaths and prescribing errors.

Mr. Broad states that the proposed regulation does not specify the qualifying requirements for the additional training that must be completed prior to the pharmacy technician being authorized to check the work of other pharmacy technicians. Rather the nature of the training is left up to the individual facilities.

It is not the board's intent to overregulate the pharmacy profession. The board is not defining the additional training requirements because it should be left up the discretion of the pharmacist-in-charge, who is ultimately responsible for the acute care pharmacy's operations to ensure the appropriate management of the pharmacy's operations. The pharmacist-in-charge is familiar with the specific operations of the acute care facility, is familiar with the skill level of each of the employees and as such is far better at determining the additional training each pharmacy technician must receive prior to allowing the technician to complete the second check. While the board does determine the minimum qualifications for licensure as a pharmacy technician, employers determine what, if any, additional training an employee technician may need to be successful in his or her employment. It would be contrary to a pharmacist's professional judgment and could result in disciplinary action, especially that of a pharmacist-in-charge to allow a pharmacy technician to check the work of another technician without proper training.

Mr. Broad states that the proposed regulation is a step towards de-skilling the pharmacists profession, and is an inappropriate response to the pharmacist shortage. Mr. Broad continues that pharmacy technicians cannot do the job of pharmacists, because they are not trained to do so.

The board believes that allowing a pharmacy technician to complete the check of pharmacy technicians in this limited capacity, would allow pharmacists be involved in direct patient medication management thereby ensuring better patient outcomes. This redirection of pharmacy staff

allows for better use of a pharmacist's training and education and is clearly not de-skilling the pharmacist profession; to the contrary it is allowing the pharmacist to be accessible, as part of a medical team, allowing other health care professionals to benefit from the specialized knowledge a pharmacist possess. Studies demonstrate that the redirection of pharmacists in the acute care hospital setting decreases hospital deaths, decreases adverse drug events, results in better patient outcomes, provides an opportunity to use skills developed through training to support the medication use process and manage drug therapy under protocol with the medical staff.

Mr. Broad states that while the proposed regulation removes the duty of checking the work of pharmacy technicians from the purview of pharmacists in the acute care setting, it does not remove the liability of those pharmacists to ensure that the work is done accurately.

The board has always maintained that the pharmacist-in-charge is responsible for pharmacy operations. This responsibility is not changed as a result of this proposed regulation. Rather the pharmacist-in-charge is empowered to determine the additional training requirements that must be completed by a pharmacy technician before they can be authorized to check another's work and whether any technicians should be allowed to check the work of other technicians. The UCSF study[3] concluded that trained pharmacy technicians have a 99.88% accuracy rate in checking the work of other technicians, higher than that of pharmacists.

Mr. Broad concludes his letter stating his earlier assertions: that the board should not promulgate these regulations as they are neither consistent with existing law nor are they within the scope of the authority of the board. The regulations could prove harmful to patients and that such regulations do not reduce the level of liability borne by pharmacists. Mr. Broad urged the board to reject the proposal.

For all of the reasons the board has cited above in response to each of Mr. Broad's concerns, the board voted to move forward with the proposed regulation.

2. In a letter dated April 17, 2006, Vicki Bermudez, RN, Regulatory Policy Specialist for the California Nurses Association provided comments in opposition to the board's proposal on behalf of the California Nurses Association. Ms. Bermudez states that the proposed regulation fails to meet the requirements of authority, reference, necessity, clarity and consistency required for rulemaking.

Although referenced in the opening of the letter, Ms. Bermudez did not specify the board's failure to satisfy the authority requirement detailed in Government Code Section 11349.1.

The board disagrees with Ms. Bermudez's assertion that the board does not have the authority to pursue these regulations. Business and Professions Code section 4005 clearly establishes the board's authority to adopt rules and regulations that are not inconsistent with the law of this state, as necessary for the protection of the public. Specifically, Business and Professions Code section 4005(a) provides that the board has the right to adopt regulations pertaining to the practice of pharmacy as well as those pertaining to establishments wherein any drug or device is compounded, prepared, furnished or dispensed. The proposed regulations are directly pertaining to the practice of pharmacy and occur in hospitals wherein drugs are prepared, furnished and dispensed. These drugs may also be compounded depending on the policies and procedures of the acute care facility. In addition to the clear authority stated above, the board also bases its authority on two separate written legal opinions both of which also confirmed the board's authority to pursue the proposed regulations. Staff counsel from the Department of Consumer Affairs concluded after researching the matter that a pharmacist is not required to personally check unit dose cassettes and floor and ward stocks filled by a pharmacy technician in an inpatient pharmacy setting. Instead the pharmacist may authorize another pharmacy technician to perform such checks. In addition, Legislative Counsel of California also reviewed the issue and concluded that a regulation may be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 (section recodified in 1998 to B & P 4115 (d)) of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians. The board's current staff counsel has also affirmed the board's authority to promulgate these regulations. Furthermore, Business and Professions Code section 4115(d) specifically requires the board to adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist.

Ms. Bermudez states that Government Code section 11349 (a) defines "reference" and alleges that the regulation proposed by the California Board of Pharmacy expands the practice of pharmacy technicians beyond that which is authorized in current statute and states that these "Tech check Tech" regulations create a new category of "super-PT" who will engage not in the performance of non-discretionary tasks but rather in the performance of tasks which the board admits necessitates "specialized and advanced training," a role currently performed by pharmacists.

The board disagrees with this assessment. The board's legal opinion from staff counsel in 1995 supports the board's authority to adopt a "tech check tech" regulation. The proposed regulation change does not expand a pharmacy technician's duties beyond the scope of non-discretionary tasks. Additionally, the UCSF study and subsequent report completed by the Director of Pharmacy Services of Cedar-Sinai Medical Center[3] concludes that the results of their latest study of specially trained pharmacy technicians demonstrates that having specially trained pharmacy technicians performing the nondiscretionary tasks of checking technician filled unit-dose medication charts frees up time for pharmacists to play a role in intercepting potential medication errors and preventing harm to patients.

Ms. Bermudez states that SB 393 in 2003 and SB 592 in 2005 included language that mirrors the "tech check tech" regulatory language proposed by the board and that both of these attempts to modify the statutes were unsuccessful. She continues on to state that it is inconceivable that legislation supported by the board was defeated but could now be adopted by the Board of Pharmacy as regulations.

The board was not the sponsor of either of these two pieces of legislation, but did have a support if amended position on SB 393 and a support position on SB 592. As stated previously, the board has two written legal opinions; one by legislative counsel and one by staff counsel that determined the board had the authority to adopt this regulation. The Board's current staff counsel agrees with these written legal opinions. And Business and Professions Code section 4115 (d) requires the board to adopt regulations further defining the role of a pharmacy technician.

Under the heading of "Necessity," Ms. Bremudez states that there has been no showing whatsoever of the need for the proposed regulation—the problem, requirement, condition or circumstance it is intended to address. She adds that hospitals already have the authority to dispatch pharmacists to patient care unit and that the proposal is unauthorized and inconsistent with Business and Professions Code Section 4001.1

Several published studies previously mentioned as well as the UCSF study[3] validate the need for pharmacists to play a role in intercepting potential medication errors and preventing harm to patients. This can be accomplished if pharmacy technicians can complete some of the other non-discretionary tasks typically assigned to pharmacists. Furthermore, public protection is the highest priority for the board, which is why the board is pursuing this regulation change. Hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the

pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. A second study conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified. Additionally, the accuracy checking rate of pharmacy technicians is 99.88%[3] clearly suggests that this regulation is in the interest of public protection.

Under the "Consistency" heading, Ms. Bermudez states that the proposed regulations are in direct conflict with the statute they purport to implement and sites California Code of Regulations section 1793.6 as the conflict.

Section 1793.6 of the CCR details the requirements for licensure as a pharmacy technician. Proposed Section 1793.8 of the CCR is not intended to increase the amount of minimum training an applicant must satisfy prior to the issuance of a pharmacy technician registration. Rather it requires that any acute care facility authorized to use pharmacy technicians to check other technicians must ensure that additional training, above and beyond what is required in current regulation must be completed prior to implementation of the program. There is no conflict.

Last, under the heading of "Clarity" Ms. Bermudez concludes that the term "clinical pharmacy program" lacks clarity and that no definition of or reference to "clinical pharmacists" or to "clinical pharmacy program" exists in statute or regulation and as such the use of these terms is confusion.

The terms used in the draft language are consistent with those used in the profession. Of the 41 written comments received as well as the nine oral comments received during the regulation hearing, not one personal, professional or public attendee had questions about these terms. They are will known terms used throughout and understood by the profession and are referenced throughout sections 4051 and 4057 of the Business and Professions Code

No additional comments by CNA were provided at the regulation hearing held on April 26, 2006.

Summary of Comments Received During the Public Hearing April 26, 2006.

1. The following individuals provided testimony in support of the proposed regulation.

- Peter Ambrose representing UCSF
- Rita Shane representing Cedars Sinai Medical Center
- Kelli Haase representing the California Society of Health Systems Pharmacists
- Anne Rosenblatt representing Cedars Sinai Medical Center
- John Cronin representing the California Pharmacists Association
- Robert Mowers representing California Society of Health Systems Pharmacists
- Darren R. Besoyan representing the UC Davis Medical Center

2. Liberty Sanchez, from the Law Offices of Barry Broad, representing the United Food and Commercial Workers Union stated opposition to the proposed regulation on behalf of the organization. Ms. Sanchez stated that they share the concept that there is a problem, but disagree with what the problem is. She added that they oppose the proposed regulations.

   Ms. Sanchez stated that it is important for pharmacists to be available in all capacities, and in particular, acute care facilities, for the more important tasks at hand. She added that the appropriate solution to the problem is hiring more pharmacists, not doling out tasks that are appropriately within the statutory and regulatory confines of the pharmacist's profession.

   The board believes that allowing a pharmacy technician to complete the check of pharmacy technicians in this limited capacity, would allow pharmacists to be available to be involved in direct patient medication management thereby ensuring better patient outcomes. This redirection of pharmacy staff allows for better use of a pharmacist's training and education. This redirection of pharmacists in the acute care hospital setting decreases hospital deaths.

   Ms. Sanchez stated that the board's obligation is to ensure that patient and consumer protection upheld with any adoption of regulations and that regulations that are adopted are not superseded or contradictory to existing statutory law. She added that the proposed regulations are clearly contradictory to existing statutory and regulatory law.

   Studies show that hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. A UCSF study documents that the accuracy checking rate of pharmacy technicians is 99.88%[3]. A follow-up study also conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent

harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified. This demonstrates the public benefit of redirecting pharmacists away from completing the nondiscretionary check that could be completed by another pharmacy technician so that the pharmacist can be involved in direct medication management during a portion of their work shift. The proposed regulations are not contradictory to existing statutory and regulatory law.

Ms. Sanchez referred to their testimony submitted on April 17, 2006 at the board's Legislation and Regulation Committee meeting and the board minutes from January 2001, October 2001, October 24 and 25, 2002 meetings that include an opinion from former Deputy Attorney General William Marcus, that the board did not have the authority to promulgate regulations. Further, page 5 of the October 24 & 25, 2002 board minutes, state: "the board decided that the proposed changes would require legislation." She added that legislation proposed by Senator Aanasted in 2003 and 2005 (SB 393 and SB 592) failed passage in the Legislature.

At the October 2001 board meeting, then Deputy Attorney General Ron Diedrich stated that there is no formal Attorney General's Opinion on this issue and that a deputy attorney general's comments are not considered an official opinion issued by the AG's Office, contrary to Ms. Sanchez's statement. Additionally, at the October 2002 board meeting, the board did not determine that the proposed regulation would require legislation. Rather, legislation was introduced independently of the board and as such the board delayed pursuing the regulation to allow the legislative process to run its course.

The board has three legal opinions that conclude that the board has the legal authority to pursue these regulations. In 1995, staff counsel from the Department of Consumer Affairs concluded after researching the matter that a pharmacist is not required to personally check unit dose cassettes and floor and ward stocks filled by a pharmacy technician in an inpatient pharmacy setting. Instead the pharmacist may authorize another pharmacy technician to perform such checks. In addition, Legislative Counsel of California also reviewed the issue and concluded that a regulation may be adopted by the California State Board of Pharmacy pursuant to Section 4008.5 (section recodified to B & P 4115(d)) of the Business and Professions Code to allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians. Current staff counsel for the board has reconfirmed the board's authority to adopt the proposed regulations.

Ms. Sanchez stated that contrary to proponent's contention that the proposed regulation will promote patient safety in the acute care setting based on the idea that there will be additional training provided to pharmacy technicians who check the work of other pharmacy technicians. Due to a lack of specificity in the proposed regulations about the advanced training and education, there is no guarantee that patient safety will be promoted by allowing pharmacy technicians to undertake this task. She expressed concern that if the proposed regulations pass, there would be additional requests in the future to expand the duties of technicians.

Studies show that hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. A UCSF study documents that the accuracy checking rate of pharmacy technicians is 99.88%[3]. A follow-up study also conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified. This demonstrates the public benefit of redirecting pharmacists away from completing the nondiscretionary check that could be completed by another pharmacy technician so that the pharmacist can be involved in direct medication management during a portion of their work shift.

Ms. Sanchez stated that the underlying published study is not sufficient to make such a sweeping change in California. She added that the underlying published study in 1998 observed only 39 pharmacy technicians, 29 pharmacists and approximately 190 thousand doses of medication. There was only a distinction of 0.3 percent in the accuracy rate of the pharmacist and the pharmacy technicians were above 99 percent. Ms. Sanchez added that the only rational for this regulation is to reduce cost by reducing the need to have multiple pharmacists in the acute care setting.

The board is not moving forward with the proposed regulations based solely on the UCSF study[3], which was published in 2002. However it is significant to note that both control groups, pharmacists and pharmacy technicians were extremely proficient as "checkers".

As indicated previously, there are several studies and published articles that document the benefits of a pharmacist's role in direct patient care.

Specifically, studies show that hospitals having pharmacists in patient care areas demonstrate a 45% decrease in medication errors and a 94% decrease in medication errors that adversely affect patient outcomes[1], and medication prescribing errors decrease by 66% when the pharmacist is a full member of the patient care team in medical Intensive Care Units [2]. Another study documents that the accuracy checking rate of pharmacy technicians is 99.88%[3]. The results of the UCSF study[3] further verify that the use of pharmacy technicians as proposed is in the best interest of public protection. A follow-up study also conducted by UCSF et. al[4] demonstrated the impact of pharmacist on prescribing and administration documented that pharmacist intercepted 1855 errors, 682 of which prevented potential harm including the prevention of four deaths the prevention of permanent harm in 28 patients, temporary harm in 590 patients and prevented an increase in the length of a patient's hospital stay in 60 encounters. An additional 834 medication errors were prevented with the level of harm unspecified. There currently are five states that allow pharmacy technicians to be used in the proposed or very similar capacity. In Minnesota the program has been in affect over 14 years with no complaints, and in Kentucky technicians have checked technicians with no complaints in over ten years. Additionally, the American Society of Health-System Pharmacists and the California Society of Health-System Pharmacists support the role of the technician in checking unit dose medication cassettes. (Professional policy 9801, October 1998.) This demonstrates the public benefit of redirecting pharmacists away from completing the nondiscretionary check that could be completed by another pharmacy technician is not merely a cost savings measure, but at times a life saving measure.

Ms. Sanchez stated that liability issues are a concern for both the pharmacist and the nurse. Nurses will be the final person to administer the medication to the patient, so they will be expected to check the medication more thoroughly.

The nurse will continue to be the final person to administer the medication to the patient. The pharmacist-in-charge is responsible for the overall pharmacy operations and will retain this responsibility. Given that the error rate documented in the UCSF study[3] are the same whether a pharmacist or a trained pharmacy technician complete the second check proposed, the level of accountability for the nurse will not change. As a health care professional, a nurse is expected to check the medication dosing which is part of a nurse's duties.

3. Martha Mason, Pharmacist, San Quinton State Prison

Ms. Mason stated that the prison has 5000-6000 patients. She expressed concern regarding technicians checking other technicians because she

often finds errors in technicians' work. She added patients in the prison system are a captive audience and sometimes may not be aware that they were administered the wrong prescription. She expresses concern that there would be more complaints about lack of care and she added that mistakes are very common.

The testimony is not relevant as the proposed regulation only affects operations in an acute care hospital pharmacy setting.

Summary of Comments Received During the 15-Day Comment Period – Availability of Documents Added to Rulemaking File.

The board received one written comment expressing concern about the proposed changes.

In a letter dated August 11, 2006, Vicki Bermudez, RN, Regulatory Policy Specialist for the California Nurses Association provided comments in opposition to the board's proposal on behalf of the California Nurses Association. A portion of Ms. Bermudez's letter is outside the scope of the 15-Day Comment noticed on July 25, 2006. As such only those comments relevant to the 15-Day Comment Period will be addressed.

Ms. Bermudez refers to the Bion Gregory Legislative Counsel opinion (Gregory Opinion) dated August 14, 1995, which is being added to the rulemaking file and states that this legal opinion defines "supervise" using the "usual or ordinary meaning" and cites the definition from Webster's Third New International Dictionary, p. 2296). Ms. Bermudez continues to also quote the definition used for "direct." Ms. Bermudez concluded that the reasoning for the Gregory Opinion support CNA's position for several reason, the most important point being the ordinary meaning and understanding of "direct" and "supervision". She continues to stated that Section 4008.4 referenced in the legal opinion was repealed by statutes of 1996 during the re-codification of the Pharmacy Law and that the area of law addressing Pharmacy Technicians was also amended during the same legislative session to remove the distinctions made in supervision and registration requirements between community Pharmacy Technicians and inpatient Pharmacy Technicians.

The board disagrees with Ms. Bermudez's conclusions for several reasons. First, Ms. Bermudez accurately reports a portion of the legal opinion prepared by Legislative Counsel, but omits a very significant portion of the opinion. Specifically, Ms. Bermudez fails to cite the conclusion of this legal opinion. Specifically, the legal opinion prepared by Legislative Counsel essentially walks the reader through the arguments both in favor of and opposed to the matter. At the conclusion of the legal opinion however Legislative Counsel concludes that the regulation may be adopted by the California State Board of Pharmacy to

allow a pharmacist to authorize an inpatient pharmacy technician to check certain tasks performed by other inpatient pharmacy technicians.

Current staff counsel has confirmed the legal opinion prepared by Legislative Counsel as relevant even given the re-codification of the Business and Professions Code as well as changes in requirements for pharmacy technicians. Additionally, Section 4008.4 was not repealed during the re-codification as stated by Ms. Bermudez. It was however renumbered to B & P Code section 4007(a) & (b).

Ms. Bermudez then states that while the knowledge of the law does not necessarily prepare the attorney for the knowledge of the work performed by healthcare technicians, placing or replacing medications into patient hospital unit that are going to be used by physicians and nurses involves numerous steps where errors can occur after "removing the drug or drugs from stock" in the pharmacy. Ms. Bermudez concludes that the opinions added to the rulemaking, the Department of Consumer Affairs Legal Opinion and the Gregory Opinion and all references to the court case decision are not relevant to this regulatory action and that even if portions of it were relevant, they would support CNA's position that the Pharmacy Board does not have the authority to expand the scope of Pharmacy Technician practice by regulatory rather than statutory means.

The board disagrees with this conclusion. The board is uncertain about why the CNA concludes that the Department of Consumer Affairs Legal Opinion is not relevant, as no justification or rational was provided for this statement. Both legal opinions are still relevant today as confirmed by our current staff counsel who also concluded that the board has the statutory authority to adopt the proposed regulation.

Ms. Bermudez's next comments relevant to the 15-Day Comment period discuss "The economic arguments that are made by the California Society of Health Systems Pharmacist should be irrelevant to the California Board of Pharmacy. The Board's mission is to protect consumers not to protect the profits of hospitals and hospital pharmacies."

The testimony added to the rulemaking file by the CSHP makes not mention of their support of the regulation being one based on economics, rather CSHP notes that it is "encouraged that the board recognizes this as a critical Consumer Protection issue and has demonstrated their support of inpatient health system pharmacy technicians…"

Mr. Bermudez further discusses the CSHP written testimony added to the rulemaking file and the list of facts contained on page 6 of the testimony under the section titled Support of California to Adopt Medication Safety Regulations where the following statistics are provided:

> "68% of medication errors occur when the prescriber writes the order. 38% of medication errors offer when the medication is administered to the patient."

Ms. Bermudez states that this is a total of 100% and states that "these advocated would have us believe that there are no dispensing errors, which is absurd and in direct contradiction to other materials contained in the rulemaking file." Ms. Bermudez states that the CNA believes that the material submitted by the CSHP is contradictory and flawed and adds nothing to support this rulemaking proceeding.

The board disagrees. First, the board did not decide to pursue the proposed regulation based on the two statistics cited above, but rather on the overwhelming amount of evidence that supports the value of a specially trained pharmacy technician checking the work of other technicians thereby allowing the pharmacist to be redeployed to be involved in direct patient care as demonstrated both by the CSHP as well as several studies. Additionally, Ms. Bermudez is assuming that the two statistics listed above are additive. The statistics listed above could rather be interpreted that 68% of medication errors occur when prescriber writes the order, and 38% of those medication errors occur when as a result of the order, the medication is administered to the patient. The remaining 30% of the errors are caught prior to the medication being administered to the patient.

Ms. Bermudez concludes her letter stating that the CNA is extremely disappointed to see that the Pharmacy Board has included "legal" arguments based on (1) statutes that have been repealed and (2) on specific Pharmacy Technician statutory language that was subsequently and substantively amended. Ms. Bermudez continues to state that it is unfortunate that these legal opinions have been suddenly offered during a second 15 day period for comments, especially given that the materials were not widely distributed to all interest stakeholder who have submitted comments.

The board disagrees with Ms. Bermudez's summary comments. First, the statutes Ms. Bermudez states were not repealed as indicated. Rather as part of a re-codification of pharmacy law, the former section B & P 4008.4 was renumbered to B & P 4007 (a) & (b). In addition, current staff counsel has reaffirmed the board's authority to pursue these regulations. Second, the board did in fact include these legal opinions as part of the information hearing held on this regulation at the February 1 & 2, 2006 board meeting. These opinions were included on the board's web site as part of the board packet material.

Local Mandate:

None

Business Impact:

This regulation will not have a significant adverse economic impact on businesses. This determination was based on the absence of testimony indicating adverse economic impact regarding these rulemaking proposals at the information hearing held by the board and during the 45-day comment period as well as the hearing held on April 26, 2006.

Specific Technologies or Equipment:

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to the affected persons than the proposed regulation.

Attachments

1. Bond C.A. et al. Medication Errors in United States Hospitals Pharmacotherapy 2001;21:1023-36
2. Leape LL.et al. Pharmacists Participation on Physician Rounds and Adverse Events in Intensive Care Units. The Journal of the American Medical Association 1999;282:267-270
3. Ambrose PJ, et al. Evaluating the accuracy of technicians and pharmacists in checking unit dose medication cassettes. AM J Health-Syst Pharm 2002;59:1183-1188 (Also referred to as the UCSF study)
4. Ambrose PJ, et al Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medication in the Hospital Setting, Summary of Results June 21, 2004 – January 1, 2006.
5. Kucukarslan SN, et al. Pharmacist Participation on Physician Rounds and Adverse Drug Events in the Intensive Care Unit. Arch Intern Med 2003;163:2014-2018